

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising a vehicle that comprises (a) an amphipathic oil that is water dispersible and ethanol insoluble, (b) microcrystalline wax, and (c) a pharmaceutically acceptable non-aqueous carrier; said vehicle having stably dispersed therein an antibacterial substance in an antibacterially effective amount.
2. The composition of Claim 1 that is suitable for administration by intramammary infusion to an udder of a milk producing animal for treatment and/or prevention of a bacterial disease of the udder.
3. The composition of Claim 2 wherein the bacterial disease is mastitis.
4. The composition of Claim 1 that is suitable for otic administration for treatment and/or prevention of an infection of an ear.
5. The composition of Claim 1 wherein the antibacterial substance is selected from the group consisting of natural and synthetic penicillins and penicillin-type antibiotics, cephalosporins, macrolides, lincosamides, pleuromutilins, polypeptides, polymixins, sulphonamides, chloramphenicol, thiamphenicol, florfenicol, tetracyclines, quinolones, fluoroquinolones, tiamulin, ciprofloxacin, colistin, domeclocycline, mafenide, methacycline, norfloxacin, ofloxacin, pyrimethamine, silver sulfadiazine, sulfacetamide, sulfisoxazole, tobramycin, vanemulin, oxazolidinones, aminoglycosides and aminocyclitols, amphenicol, ansamycin, carbapenem, cephamycin, vancomycin, monobactam, oxacephem, systemic antibacterials, nitrofuransulfones, marbofloxacin, tautomers, stereoisomers, enantiomers, salts, hydrates and prodrugs thereof, and combinations thereof.
6. The composition of Claim 1 wherein the antibacterial substance is a natural or synthetic penicillin or penicillin-type antibiotic selected from the group consisting of penicillin, benzyl penicillin, phenoxymethyl penicillin, coxacillin, nafcillin, methicillin, oxacillin, amoxycillin, temocillin, ticarcillin, penicillinase-stable penicillins, piperacillin, azlocillin, mezlocillin, carbenicillin, temocillin, ticarcillin, streptomycin, neomycin, framycetin, genatamicin, apramycin, amikacin, spectinomycin and ampicillin.

7. The composition of Claim 1 wherein the antibacterial substance is a macrolide selected from the group consisting of tylosin, tilmicosin, aivlosin, erythromycin, azithromycin, spiramycin, josamycin and kitasamycin.
8. The composition of Claim 1 wherein the antibacterial substance is a pleuromutilin selected from the group consisting of tiamulin and valnemulin.
9. The composition of Claim 1 wherein the antibacterial substance is a polymixin selected from the group consisting of polymixin B and polymixin E.
10. The composition of Claim 1 wherein the antibacterial substance is a sulfonamide selected from the group consisting of sulfamethazine, sulfadiazine, sulfamethoxypyridazine and sulfatroxazole, and is present alone or in combination with trimethoprim.
11. The composition of Claim 1 wherein the antibacterial substance is a tetracycline or derivative thereof selected from the group consisting of tetracycline, chlortetracycline, oxytetracycline, doxycycline and minocycline.
12. The composition of Claim 1 wherein the antibacterial substance is an oxazolidinone selected from the group consisting of eperezolid, linezolid, N-((5S)-3-(3-fluoro-4-(4-(2-fluoroethyl)-3-oxy-1-piperazinyl)phenyl-2-oxy-5-oxazolidinyl)methyl)acetamide, (S)-N-((3-(5-(3-pyridyl)thiophen-2-yl)-2-oxy-5-oxazolidinyl)methyl)acetamide and (S)-N-((3-(5-(4-pyridyl)pyrid-2-yl)-2-oxy-5-oxazolidinyl)methyl)acetamide hydrochloride.
13. The composition of Claim 1 wherein the antibacterial substance is 2,4-diaminopyrimidine.
14. The composition of Claim 1 wherein the antibacterial substance is a cephalosporin selected from the group consisting of ceftiofur and salts thereof, cephalixin, cephradine, cefquinome, cephacetrile, cephalonium, cefuroxime, cefazidime, cefoperazone, sodium cephemethcarboxylate, cephem heptahydrate, cephalosporin di- and tri-hydrate, cephadroxil monohydrate, cephalolin sodium monohydrate, cefiximine, ceftaxime, ceftizoxime, ceftriaxone, o-formylcefamandole, salts of 3-acetoxymethyl-7-(iminocetamido)-cephalosporanic acid derivatives, monohydrate of 7-(D- α -amino- α -(p-hydroxyphenyl)acetamino)-3-methyl-3-cephem-1-carboxylic

acid, hydrochloride salt of syn-7-((2-amino-1-thiazolyl)(methoxyimino)acetyl)-amino)-3-methyl-3-cephem-4-carboxylic acid, crystalline cephem acid addition salts, (pivaloyloxy)methyl-7-beta-(2-(2-amino-4-thiazolyl)acetamido)-3-(((1-(2-(dimethylamino)ethyl)-1H-tetrazol-5-yl)thio)methyl)-3-cephem-4-carboxylate, cephalixin, cephalixin monohydrate, 7-(D-2-naphthylglycylamino)-3-methyl-3-cephem-4-carboxylic acid tetrahydrate, tautomers, stereoisomers, enantiomers, salts, hydrates and prodrugs thereof, and combinations thereof.

15. The composition of Claim 1 wherein the antibacterial substance is selected from the group consisting of ceftiofur and pharmaceutically acceptable salts thereof, and combinations thereof.
16. The composition of Claim 15 wherein the antibacterial substance is present at a concentration of about 1 to about 1000 mg/ml.
17. The composition of Claim 15 wherein the antibacterial substance is present at a concentration of about 5 to about 750 mg/ml.
18. The composition of Claim 15 wherein the antibacterial substance is present at a concentration of about 10 to about 100 mg/ml.
19. The composition of Claim 1 wherein the antibacterial substance is ceftiofur hydrochloride.
20. The composition of Claim 1 wherein the antibacterial substance is ceftiofur crystalline free acid.
21. The composition of Claim 1 wherein the amphipathic oil is a polyglycolized glyceride prepared by an alcoholysis reaction of natural triglycerides with polyethylene glycols.
22. The composition of Claim 21 wherein the polyglycolized glyceride is selected from the group consisting of Labrafil™ M-1944CS, Labrafil™ M-1966CS, Labrafil™ M-1969CS, Labrafil™ M-1980CS, Labrafil™ M-2125CS, Labrafil™ WL-2609BS, Labrafil™ ISO, polyglycolized glycerides substantially equivalent thereto, and combinations thereof.
23. The composition of Claim 21 wherein the polyglycolized glyceride comprises a main fatty acid component of oleic acid or linoleic acid.

24. The composition of Claim 21 wherein the polyglycolized glyceride comprises a main fatty acid component of oleic acid.
25. The composition of Claim 21 wherein the polyglycolized glyceride is pegicol 5-oleate.
26. The composition of Claim 1 wherein the non-aqueous carrier is selected from the group consisting of vegetable oils, mineral oils, medium to long chain fatty acids and alkyl esters thereof, propylene glycol di-esters of medium to long chain fatty acids, mono-, di-, and triglyceryl esters of fatty acids, polyethylene glycols, and combinations thereof.
27. The composition of Claim 1 wherein the non-aqueous carrier is a vegetable oil selected from the group consisting of cottonseed oil, corn oil, sesame oil, soybean oil, olive oil, coconut oil, fractionated coconut oils, peanut oil, sunflower oil, safflower oil, almond oil, avocado oil, palm oil, palm kernel oil, babassu oil, beechnut oil, linseed oil, rape oil and combinations thereof.
28. The composition of Claim 1 wherein the non-aqueous carrier is cottonseed oil.
29. The composition of Claim 1 wherein the non-aqueous carrier comprises capric acid in an amount of about 20% to about 45% and caprylic acid in an amount of about 45% to about 80% by weight of the non-aqueous carrier.
30. The composition of Claim 1 wherein the amphipathic oil constitutes about 0.01% to about 99% weight/volume of the composition.
31. The composition of Claim 1 wherein the amphipathic oil constitutes about 1% to about 80% weight/volume of the composition.
32. The composition of Claim 1 wherein the amphipathic oil constitutes about 3% to about 25% weight/volume of the composition.
33. The composition of Claim 1 wherein the microcrystalline wax constitutes about 0.01% to about 50% weight/volume of the composition.
34. The composition of Claim 1 wherein the microcrystalline wax constitutes about 1% to about 40% weight/volume of the composition.
35. The composition of Claim 1 wherein the microcrystalline wax constitutes about 3%

- to about 15% weight/volume of the composition.
36. The composition of Claim 1 wherein the non-aqueous carrier constitutes about 0.5% to about 99% weight/volume of the composition.
 37. The composition of Claim 1 wherein the non-aqueous carrier constitutes about 10% to about 95% weight/volume of the composition.
 38. The composition of Claim 1 wherein the non-aqueous carrier constitutes about 40% to about 90% weight/volume of the composition.
 39. The composition of Claim 1 that further comprises at least one excipient selected from the group consisting of antioxidants, preservatives, stabilizers, wetting agents, lubricants, emulsifiers, salts for influencing osmotic pressure, coloring agents, alcohols and buffering agents.
 40. The composition of Claim 1 that further comprises at least one excipient selected from the group consisting of tocopherols, ascorbyl palmitate, butyl hydroxyanisole, butyl hydroxytoluene, benzoic acid and derivatives thereof, ethylenediamine, sodium bisulfite, sulfur dioxide, maleic acid, propyl gallate, magnesium stearate, talc, silicic acid and carbohydrates.
 41. An article of manufacture comprising a container or delivery device having an oxygen permeable wall, and having contained therein a composition of Claim 1.
 42. The article of Claim 41 wherein said wall is constructed of an oxygen permeable material comprising polyethylene.
 43. The article of Claim 41 wherein the composition exhibits extended chemical and/or physical stability by comparison with an otherwise similar reference composition lacking one or both of the amphipathic oil and the microcrystalline wax.
 44. A method of treatment or prevention of a bacterial infection in a subject, the method comprising administration of a composition of Claim 1 to a fluid-containing organ of the subject via a natural exterior orifice of the organ, wherein upon said administration the composition disperses in said fluid.
 45. The method of Claim 44 wherein said administration effects targeted delivery of the antibacterial substance to a site of said bacterial infection in said organ.

46. The method of Claim 44 wherein said bacterial infection is present in an udder of a milk-producing animal and wherein said administration is by intramammary infusion.
47. The method of Claim 46 wherein said bacterial infection is manifested as mastitis.
48. The method of Claim 44 wherein said bacterial infection is present in an ear and wherein said administration is by otic infusion or injection.